## Pilot Study: Stenting Succeeds in Acute Stroke

BY MITCHEL L. ZOLER

HOLLYWOOD, FLA. — Intracerebral stenting during acute stroke successfully restored cerebral blood flow in all 20 patients treated in a pilot study.

Of the 20 patients enrolled in this first phase of the Stent-Assisted Revascularization for Acute Stroke study, 14 had an average reduction in their National Institutes of Health Stroke Scale (NIHSS) score of six to seven points, a clinically meaningful result, Dr. L. Nelson Hopkins reported at ISET 2009, an international symposium on endovascular therapy.

On the basis of this promising result, Dr. Hopkins and his associates received



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DR. HOPKINS

permission from the Food and Drug Administration to start a second phase of the study with another 20 patients who will be treated in much the same way. Dr. Hopkins is professor and chairman of neurosurgery at the State University of New York at Buffalo.

In the study, selected acute stroke patients with a thrombus occlusion in a cerebral artery underwent angioplasty using a Gateway balloon catheter, followed by placement of a Wingspan self-expanding nitinol stent inside the occlusion.

Both the balloon and stent, made by Boston Scientific, received humanitarian device exemption approval from the FDA in 2005. The devices are labeled for the treatment of symptomatic intracranial atheromatous disease.

The concept of stenting occluded cerebral arteries during the acute phase of a stroke developed when Dr. Hopkins and his associates began to place stents in acute stroke patients after their occlusions failed to respond to standard pharmacologic thrombolysis and mechanical thrombus removal.

"We found that stents worked when all else failed, so we thought why not stent primarily," said Dr. Hopkins, director of the Toshiba Stroke Research Center in Buffalo

In some cases, a clot retrieval device will simply bounce off a clot and be unable to remove it. But a stent does not bounce off. It pushes the clot aside and opens flow through the blocked artery, which then often leads to clot lysis. Once the thrombus is stented, the treated patients have at least Thrombolysis in Myocardial Infarction (TIMI) grade 2 flow, and in many cases they have unimpeded, TIMI 3 flow, he said.

The pilot study enrolled patients with an NIHSS score higher than 8 who were treated more than 3 hours after onset of symptoms. Patients with a lower NIHSS score could be enrolled if they also had aphasia and upper extremity paresis.

Another key enrollment criterion was preserved cerebral blood volume despite diminished cerebral blood flow. A relatively high level of cerebral blood volume is a marker for collateral flow to the ischemic region of the brain. That flow keeps the tissue alive and salvageable. Cerebral blood flow and volume were

measured with a 320-slice CT unit made by Toshiba and installed at the Buffalo facility. The high resolution of this "dynamic volume" CT machine allows assessment of both cerebral anatomy and physiology, Dr. Hopkins said.

Patients with "high cerebral blood volume have excellent potential for salvage if their [cerebral] perfusion is reestablished," Dr. Hopkins pointed out. The researchers require a minimum cerebral blood flow of about 15 mL/100 g per minute for study inclusion. With reliance on CT measures of blood flow and volume, the time of stroke onset and the delay to treatment is much less important, he said.

Dr. Hopkins disclosed that he is a consultant to, receives research support from, and has a financial interest in, Boston Scientific and several other companies.

